

## **REMARKS**

### **I. Status of the Claims and Support for the Amendments**

Claims 9, 12–14, 18, and 20 are currently amended.

Claims 1–4, 8, 9, 12–14, 18, 20, 23, 28, and 29 are currently pending.

Support for the amendments to the claims is found at page 2, lines 1–8 and at pages 5, 6, and 18.

### **II. Response to the Office Action**

Applicant firstly expresses gratitude to the Examiner for the suggestions and guidance she provided during a telephone conversation with the undersigned patent agent, conducted on March 29, 2004. The amendments to the claims are believed to be in accordance with the suggestions made by the Examiner during that telephone conversation.

#### **A. Rejoinder of claims 23, 28, and 29**

Claims 23, 28, and 29 have been withdrawn from consideration as being drawn to a non-elected invention. In response applicant notes the withdrawal and requests rejoinder of these claims in accordance with *MPEP* §821.04, when claim 1 is determined to be allowable. *MPEP* §821.04 recites, in pertinent part, that: “if applicant elects claims directed to [a] product and a product claim is subsequently found allowable, withdrawn process claims which depend from or otherwise include all the limitations of the allowable product claim will be rejoined.”

Given that claim 23 recites the phrase “with a peptide of claim 1” (and claims 28 and 29 depend from claim 23), Applicant believes that these claims meet the requirements of *MPEP* §821.04 that these process claims “*depend from or otherwise include all the limitations of the allowable product claim*”, namely claim 1. Accordingly, once claim 1 is found allowable, claims 23, 28, and 29 may properly be rejoined and allowed.

**B. Rejection under 35 U.S.C. § 112, first paragraph**

Claims 1–4, 8, 9, 12–14, 18, and 20 are rejected under 35 U.S.C. § 112, first paragraph as allegedly containing subject matter that is “not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected to make and/or use the invention.”

The rejection recites, *inter alia*, that:

there is a high level of unpredictability in diagnosing subjects with autoimmune diseases including rheumatoid arthritis using the claimed citrullinated peptides and Applicant does not provide direction or guidance to do so.

There is no guidance in the specification in peptides longer than 18 amino acid residues as to what amino acid residues outside of the core motif-containing amino acid residues result in a functional peptide...Accordingly, there is a high level of unpredictability in making and/or using the claimed citrullinated peptides and Applicant does not provide direction or guidance to do so. There is insufficient guidance in the specification as to how to use the instant invention.

Applicant respectfully traverses.

Taking the current Office communication and the undersigned’s telephone conversation with the Examiner, it is Applicant’s understanding that the reason for rejection is that the Examiner does believe that there is support in the specification to enable one of skill in the art to make and/or use peptides over 18 amino acid long or to use the claimed peptides as the sole means to “diagnose” rheumatoid arthritis. While Applicant, does not concede that this is the case, in the interest of proceeding to patent Applicant has amended the claims to address the Examiner’s concerns.

In view of these amendments to the claims, Applicant believes that the current claims are fully enabled as required under 35 U.S.C. § 112, first paragraph. Firstly, Applicant notes that as currently amended all claims are drawn to peptides having the sequence of SEQ ID NO:4 that

“consist of” 18 amino acids (*e.g. see* claim 1). Moreover, such peptides are fully enabled by the Specification and functional examples include peptides having the sequence of SEQ ID NO:12 and SEQ ID NO:17. Accordingly, Applicant believes that the instant rejection is overcome as it pertains to the peptide claims.

Similarly, as currently amended, Applicant believes that the “kit” claims (*i.e.* claims 12–14 and 20 are also fully enabled. As now amended these claims recite, in pertinent part, a “kit for use in detecting autoantibodies present in the sera of patients with rheumatoid arthritis.” One of ordinary skill in the art would appreciate, in view of the teachings of the instant application one of skill in the art is provided with all that is necessary to enable the use of a peptide according to SEQ ID NO:4 to detect autoantibodies present in the sera of patients with rheumatoid arthritis.

Accordingly, in view of the Amendments to the Claims and the foregoing explanation, Applicant believes that the rejection of claims 1–4, 8, 9, 12–14, 18, and 20, under 35 U.S.C. § 112, first paragraph, have been overcome and may now properly be withdrawn.

#### **C. Rejection under 35 U.S.C. § 112, second paragraph**

Claim 9 is rejected under 35 U.S.C. § 112, second paragraph as allegedly being indefinite for the recitation “comprising”. Applicant replies as follows.

In response to the rejection of claim 9, Applicant has amended that claim so that the germane portion of the claim now recites “[a] peptide according to claim 1 consisting of the amino acid sequence... .” Accordingly, Applicant believes that the rejection of claim 9, under 35 U.S.C. § 112, second paragraph, has been overcome and may now properly be withdrawn.

**D. Conclusion**

In view of the foregoing AMENDMENTS and REMARKS, Applicant believes that all rejections of the claims have been overcome and that they are now in condition for immediate allowance. Consequently, Applicant respectfully requests favorable reconsideration of the instant application and issuance of a Notice of Allowance therefor.

After review of the instant response, if the claims and/or application is found by the Examiner to be deficient for any reason, Applicant respectfully requests that the Examiner contact the undersigned patent agent at (713) 787-1589 with any questions, comments or suggestions relating to the referenced patent application, prior to issuing an advisory action for the case.

It is Applicant's hope that any remaining issues might be resolved without the need for a further office communication..

Respectfully submitted,



Matthew L. Madsen  
Reg. No. 45,594  
Patent Agent for Assignee  
INNOGENETICS N.V.

HOWREY SIMON ARNOLD & WHITE, LLP  
750 Bering Drive  
Houston, Texas 77057-2198  
(713) 787-1400

Date: Apr. 1 29, 2004